D-MUe-EVRF-06

MANUAL EVRF

CE 1639

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We thank you for your confidence

The PRODUCT includes a plan of two years guarantee, covering:

- ☞ - All the spare parts.
- ☞ - Working-hours.
- ☞ - Expenses for displacement or transport.

This guarantee is only applicable on the condition that the completion bond is turned over to
F care systems and that all the clauses of safety measures were applied strictly. For this we ask you to read the chapter *SAFETY* of this *manual*.

For any further information or any technical problem concerning the product, we will stay fully at your disposal.

READ THE INSTRUCTIONS BEFORE CONNECTING THE INSTRUMENT IN SERVICE

THE USE OF THIS DEVICE IS RESERVED ONLY TO PEOPLE WHO ARE HAVING THE ABILITY AND KNOWLEDGE ON THE SUBJECT OR ACTING WITH THE AUTHORITY OF A COMPETENT PERSON.

ALL THE INSTRUCTIONS OF THIS MANUAL MUST BE FOLLOWED STRICTLY.

CARD-INDEX OF GUARANTEE

This card must be obligatory return to F care systems within 15 days after reception of the EVRF.

F care systems NV

Kontichsesteenweg 54

B-2630 - AARTSELAAR - Belgium

NAME :
……

ADDRESS :
……
……

……
……
POSTAL CODE : ……..
TOWN :……
COUNTRY :
……..

EVRF N° : ……..
received on : …….

I, undersigned (name and function)..... state to have taken knowledge of the **chapter of safety of this user's manual** and I engage, in the name of my establishment, to apply it and to make it apply.

NAME and SIGNATURE STAMP

Summary

WE THANK YOU FOR YOUR CONFIDENCE 2

THE PRODUCT INCLUDES A PLAN OF TWO YEARS GUARANTEE, COVERING: 2

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1. SECURITY INSTRUCTIONS

1.1. Electrical Security

- Check if the disposals taken for the electrical security from the place where the apparatus will be set up, are conform to the actual regulations, **before the apparatus is taken in service.**
- Risk of damaging the apparatus in case of excessive points of tension or mains cut.
- Check if the tension and the frequency indicated at the back of the apparatus, are conform to the electricity mains of the region.
- The apparatus must only be used with the cable provided together with the device. It must always be connected to a ground plug, conform to the local regulations for medical premises.
- In case of extension of the power supply cable, the leak currents can be increased. The apparatus, in this case, is not conform anymore to security standards.

1.2. Electromagnetic disruption

- The apparatus is equipped with a filter for mains suppression. To avoid any eventual disruption, don't use the apparatus near to another sensitive high frequency device. (Doppler, Peacemaker, etc.)

1.3. Protection against explosion

- The apparatus must be disconnected from the power to disinfect the place where the unit is located.
- Don't use the apparatus at places where flammable gas or steam is present.

1.4. Security by installation

- The apparatus can not be installed at a location with high atmospheric dampness.
- Avoid penetration of any liquids inside the apparatus because it is not watertight.
- Don't wet the apparatus.
- If however a liquid had penetrated into the apparatus, stop the treatment immediately and disconnect the apparatus from the mains. Have the apparatus checked by a competent person.
- Don't expose the apparatus to high temperatures (>40°C).
- Don't install the apparatus near a heat source (central heating...) and never under the direct light of the sun.
- Never cover the ventilation grate at the back of the apparatus. These vents must be positioned to get always a good air circulation.
- Don't expose the apparatus to rain.
- The apparatus may never undergo vibrations.
- Don't keep the apparatus in places where the temperature is lower than 10°C.

1.5. Security during use

- At the end of the treatment, make sure that you “switch off” the apparatus.
- Immediately replace any defective cable.
- It is recommended that the patient is not connected with the applied parts before the apparatus has been switched ON.
- The apparatus must only be used with accessories, maintenance parts, and consumption products, which technical security on use has been controlled and approved by a control organism, entrusted with the mission of control of the apparatus and its accessories.
- It’s important to inform the patient about the sensation he will feel during treatment with the device. The treatment is not for:
  - People who are prone to diseases.
  - People who do not understand (mentally) what will happen or who are not rational enough to distinguish between "normal" and "abnormal" (comatose patients, non-intellectual people).
  - People who can’t express themselves or reveal abnormal sensations (infants, elderly).
  - People with epilepsy, heart failure, pregnancy.
  - People who refuse the treatment.

1.6. Technical control

The user must assure the submission of the apparatus for a technical control in conformity with the medical instructions 93/42/CEE at least once a year or after each repairing.

This technical control is made of:
a) A visual control
b) A security control
c) A control of all functions
d) Measuring the exit-signals
e) Measuring of securities for overload current

The results of this control must be collated on the control formular (at the end of this manual).

This control must be realised by competent people who are recommended by the company **F CARE SYSTEMS**.

1.7. Guarantee and liabilities

Conditions of guarantee:

- The guarantee takes two years on the device and seven years on the spare parts, from the day of the purchase (mentioned on the invoice you always have to keep with you).
- Are in guarantee: manufacturing defects and the repairing of hidden defaults once they have been proved.

- Also falls under warranty: the repairing of defective components. The purchaser must inform **F CARE SYSTEMS** about the expiry date of the guarantee, by registered letter with acknowledgement of receipt.

- No compensation can be asked as a prejudice due is to the immobilization of the apparatus. The pick up and return charges are for the purchaser.

- The yearly guarantee mentioned doesn't apply for: the repair of a breakdown or mistakes due to a bad use of the apparatus or of its accessories, an erroneous interpretation of the manual, negligence or an accident, bad maintenance of the device or a repairing of the apparatus realised by an incompetent person - not recommended by F care systems.

Not covered by warranty:

- Incorrect operation of the device.

- The regulations, repairs or modifications effectuated by the purchaser or by a third party not recommended by F care systems.

- Damage of the delivered device (box, housing, display) during the impact caused by the transport or by dropping it down.

- Any external interventions, fire, lightning, flood, natural disaster, explosion, war, to many voltage, etc...

- If proved that the apparatus has been opened.

- If the identification of the apparatus has been changed or modified.

- If the guarantee form has not been returned within 5 days after the delivery date, incorrectly or incompletely filled in.

Liabilities:

- After a period of 10 years of marketing of the device, **F care systems** will not be held responsible for any errors and their consequences.

- **F care systems** can not be blamed for any eventual consequences for the device, the user or the patient; for example as wrong use of the device or the accessories, wrong interpretation or no use of the manual, bad maintenance or repair of the device by an incompetent person - not recommended by **F care systems.**

- **F care systems** can not be blamed in case of electrical discharge, cardiac sickness or allergy on a patient due to a bad manipulation, bad connections due to excessive regulations or to a wrong use of the accessories. Neither the manufacturer, nor **F care systems** will be blamed in case of transmission of infections by the needles.

1.8. Cleaning and servicing

AS SECURITY PRECAUTION, DISCONNECT THE APPARATUS FROM THE NETWORK BEFORE ANY SERVICING OR REPAIRING!

- To assure as standing guarantee for security and the quality of the apparatus, it's totally forbidden to open the device or the accessories by an incompetent person.
- Opening the device or its accessories (for servicing or repairing) is only reserved for competent people recommended by **F CARE SYSTEMS.**

Apparatus

- You can clean the external face of the apparatus with a soft, dry rag or a damp rag.
- Don't use aggressive products because they can damage the spare parts inside the device. In case of streaks or smears, use a non aggressive soapy water.
- None liquid may penetrate into the apparatus and also dry the device carefully after cleaning.

Hygiene

- The needles and catheter used are sterile and for single use. **Never use the same needles and catheter for more patients and wear gloves during the treatment.**

Waste handling

- Please, throw the single use products in the appropriate bio-medical waste bins, according to national regulations.

End of life considerations:

- At the end of its life, the product is taken out of service. European legislation and sometimes national laws arrange the basic principles on how to treat the product. Different rules apply depending on possible contamination risks. For electrical and electronic equipment, the EU Directive on WEEE deals with recovery and treatment of waste at European level.
  Recommendations:
  The user must contact the MANUFACTURER if he is unsure what to do with the product when it is taken out of service.

Fuses

- The replacement of the fuses accessible through the fuse holder of the mains power supply must be realised with a flat screwdriver. The two fuses are type F2A/250V in glass 5 mm per 20 mm.

Maintenance
The EVRF device must be controlled annually by F care systems or a company authorised by F care systems after the warranty has expired.

Transport and storage

The apparatus can be carried out and stored during 15 weeks maximum and in the following environment conditions:

- Room temperature between – 40°C and + 70°C
- Relative dampness between 10% and 100%
- Atmospheric pressure comprised between 500 hPa and 1060 hPa

After 15 weeks must the device pass the test procedure again.

1.9. In case of problems

- **The apparatus doesn't switch on :**

Check if the power cable is well connected to the device and put the switch on "I".

- **There is no output signal:**

Check first if the pen is well connected to the apparatus. If this is the case there is a problem with the pen itself, so you have to take another one.

1.10. Practical advices

- Never place the unit in direct sunlight during treatment.
- Place the machine on a solid and flat surface.
- Use the EVRF only at temperature between 10 °C – 40 °C.
- Do not expose to rain and moisture.

2. TECHNICAL CHARACTERISTICS

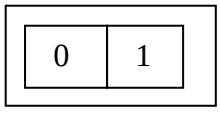
2.1. General characteristics

- Supply Voltage: 110-230V / 50-60Hz ~
- Power : 125VA
- BF type apparatus

- Protection degree against liquid penetration : IPX0
- Temporized fuse in glass.
- Work in continuous.
- Dimensions : H = 360 mm, D = 260 mm, W = 130 mm
- Weight :4 Kg
- Class IIa apparatus
- Insulation: class I

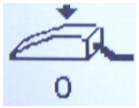
Output of the thermo-coagulation (HF) signal

Fuse reference : 2x F2A / 250V



Switch on/ Switch off button

2.2. Explanation of the Symbols

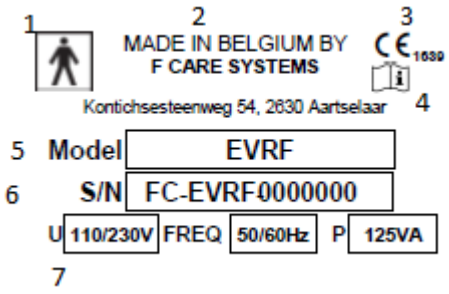
✓	Confirm
×	Cancel
↑ ↓ → ←	Select
	Reduce power
	Raise power
	Reduce impuls
	Raise impuls
	Once you press this button, the device is ready for use
	Session timer
	The number of impulse per session
	Type BF device
	CE marking
	Read manual before use
U	Allowed voltage
FREQ	Frequency
P	Maximum power

2.3. Output characteristics

This apparatus generates some high frequencies impulses whose characteristics are:

- frequency of the wave : 4 MHz
- max voltage in output : 400V (+/- 20 V)
- max time of impulse : 0,8 s (+/- 0.01 s)
- continues mode

2.4. Label explanation



1: Type BF apparatus
2: Name + address of fabricant
3: CE number
4: Read operating manual before usage
5: Model/apparatus name
6: Serial number
7: Technical specifications

2.5. Functioning

The apparatus works in the following environment:

- Room temperature comprised between +10°C and + 40°C
- Relative dampness comprised between 30% and 80%, condensation comprised
- Atmospheric pressure comprised between 700 hPa and 1060 hPa

The power supply mustn't exceed a voltage of 230V~+-10% for the rated voltage.

3. VARICOSITIES

A PRACTICAL GUIDE TO THE TREATMENT OF VARICOSITIES by
Dr. Jean Marc CHARDONNEAU

3.1. Introduction

The legs, as organs used for walking and communication, play a leading role in social life. Superficial vein disorders in the legs are a major preoccupation for our contemporaries, in particular from an aesthetic point of view. Understanding how to respond to this demand is the main purpose of this guide.

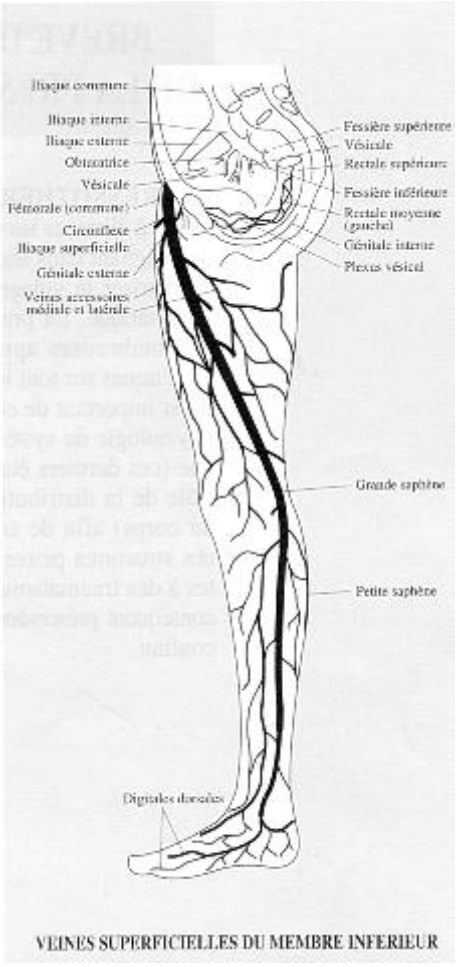
It sets out to provide practitioners with grounding in the anatomical, physiological and therapeutic elements required for a calm approach to superficial vein disorders caused by varicosities and will enable you to make effective use of the various treatments.

The common thread running through this guide is one of pragmatism

3.2. Anatomy of the venous system

3.2.1. General information on vascularisation

Three types of circulation flow through the lower limbs: arterial - venous and lymphatic.



Arterial blood flows from the aorta to the common iliac artery and then the external iliac artery before traversing the femoral canal. The femoral artery divides very rapidly into the superficial femoral artery and the (more secondary) deep femoral artery. The popliteal artery follows on from the superficial femoral artery, giving rise to two branches: the anterior tibial artery and the tibioperoneal trunk, which in turn divides into the posterior tibial artery and the peroneal artery.

Blood returns via two networks:

1. a superficial network that drains 1/10 of the blood
2. a deep or aponeurotic system that drains 9/10 of the blood and is a satellite of the arterial system.

These two networks are linked by communicating veins flowing, under normal conditions, from the superficial network to the deep network.

The lymphatic vessels drain the lymph, which comes from the interstitial tissue. Lymphangions, then collectors and finally ganglions, ensure circulation to the thoracic canal. They traditionally transport substances with a high molecular weight.

Other properties have recently been attributed to them, notably transporting immuno-competent cells. Any insufficiency or dysfunction of the lymphatic system therefore results in upsetting not only the liquid homeostasis, but also the immunological homeostasis.

3.2.2. The superficial venous network

The superficial Greater Saphenous Vein

Saphenous trunk

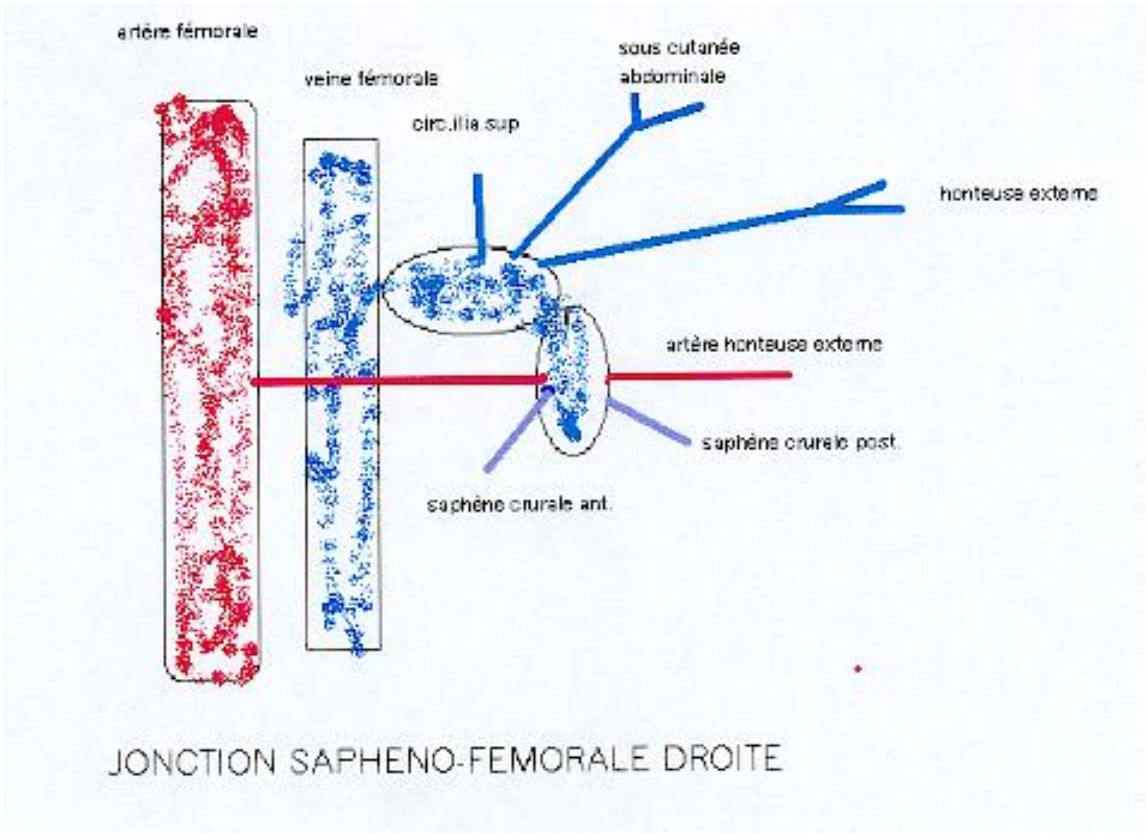
The internal saphenous (or greater saphenous) vein begins in the medial marginal vein of the dorsum of the foot and before the medial malleolus, running along the internal face of the tibia. It is accompanied along this route by the internal saphenous nerve.

It traverses the medial condyle then runs alongside the sartorius muscle and the adductor muscle and flows to Scarpa's triangle via the arch in the common femoral vein.

Collaterals of the Medial Saphenous Vein

- Leonardo's vein or posterior leg vein of the medial saphenous vein
- anterior leg vein of the medial saphenous vein
- external leg vein of the external saphenous vein

Tributaries of the Sarphenous Arch



JONCTION SAPHENO-FEMORALE DROITE

Abdominal subcutaneous vein.
Surface iliaque circumflexe vein.
External ashamed vein.
Posterior Saphenous crural.
Former Saphenous crural.

The crural veins

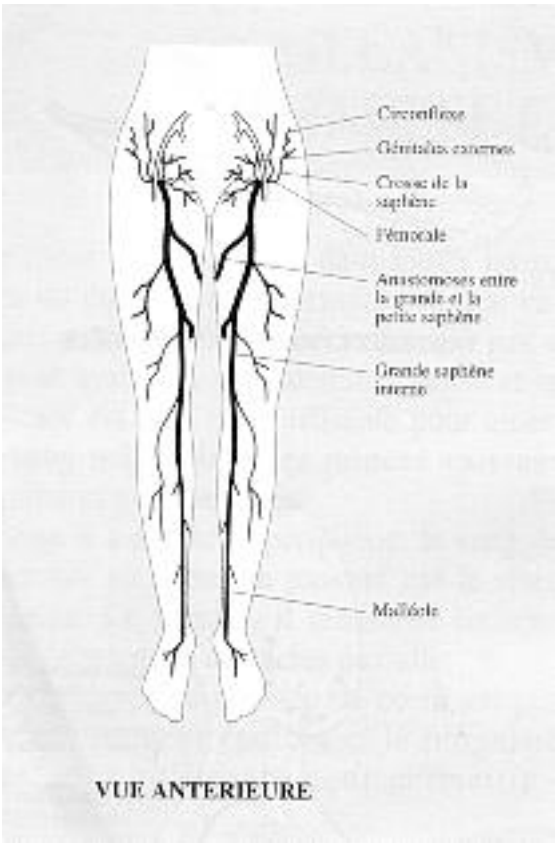
Anterior saphenous vein: antero-medial situation, it frequently terminates in the medial saphenous arch, but more rarely flows into the superficial circumflex iliac vein, the subcutaneous abdominal vein or external pudic vein

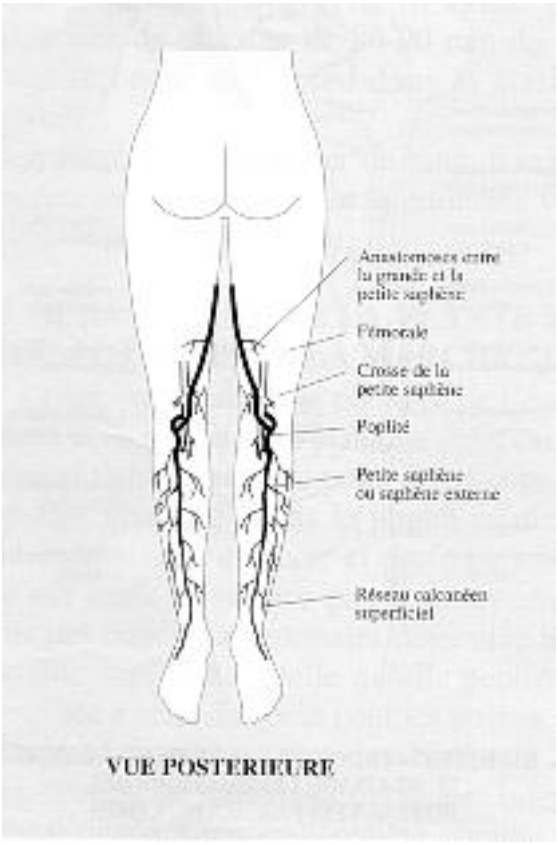
External crural arches of subcutaneous gluteal or trochanteric origin, they are often sinuous and very superficial;

posterior crural veins of the external pudic vein or the haemorrhoidal vein...

Medial varices: Giacomini's vein, Cruveilhier's vein and the posterior crural saphenous vein

The superficial lesser Saphenous Vein





Pathway

Begins opposite the posterior side of the external malleolus, following the external marginal vein. Rises obliquely upwards and inwards towards the medial posterior line. It is accompanied by the external saphenous nerve, a branch of the external sciatic popliteal nerve. It then becomes the subaponeurotic vein and flows into the popliteal vein in 60% of cases, into the collateral veins of the knee in 30%, and into the greater saphenous trunk in 10%.

Anastomotic veins

These are the veins interlinking the two saphenous veins.

- In the legs:
  - 3 oblique branches on the medial side
  - 4 transversal branches on the external side

- In the crural zone:
  - Giacomini's vein arises in the external saphenous arch, rising and ending in the upper 1/3 of the medial saphenous vein
  - The external femoral poplitic vein rises on the posterior side of the thigh as far as the fold in the buttocks.

The Venule of the Poplitea Fossal

They originate from an anastomosis with crural veins or a posterior crural perforator, and ending in various ways in the external saphenous vein, the gemellary veins, the peroneal vein or the reticulum of the calf.

The Perforating Veins

Anastomoses between the deep and superficial network with perforation of a fascia. There are two types:

1. direct - linking directly the saphenous veins to the deep network.
2. indirect - linking the two networks through intermediate trunks, general small in calibre.

They vary widely from one individual to another. They are very numerous:

- in the feet: 50 to 70 in general with valves
- in the legs: retro-tibial: Cockett (2 to 4) and Boyd (2 to 5), muscular: solear (3) - gemellary (5 to 6) - perforating the popliteal fossa
- In the crural zone: Hunter's (or Dodd's) perforator - perforators of the deep femoral vein and the femoral vein (with an accessory arch)

3.2.3. The Deep Veinous System

90% of the blood uses this return route. The deep veins have valves.

- The leg veins contain a large number (10)
- The popliteal vein from 0 to 4
- The superficial femoral and common vein from 2 to 6
- The deep femoral vein 3
- The iliac veins rarely have valves.

In the legs the veins are satellites of the arteries of the same name. In principle, there are two veins for one artery.

The anterior tibial veins: these begin at the back of the foot from the confluence of the deep dorsal metatarsal veins. They traverse the medial part of the anterior face of the ankle and rise alongside the muscles of the anterior section of the leg. At the upper edge of the interossal ligament they join the venous tibial-peroneal trunk.

The posterior tibial veins: they start at the confluence of the plantar veins, rise in the posterior section of the leg and in the upper 1/3 of the leg, they form the tibial-peroneal trunk with the peroneal veins.

The peroneal veins start out narrow and progressively increase in calibre from the influx of veins from the solear muscle. They run across the posterior face of the leg muscle and help to form the tibial-peroneal trunk.

At the knee, all of the leg veins join (near the ring of solear muscle or above the articular interline), giving rise to the popliteal vein.

It may be double (1/3) or even triple. It receives many tributaries: the medial and external gemellary veins - the articular veins - the external saphenous vein - the popliteal fossa vein.

At the thigh: the superficial femoral vein follows on from the popliteal vein at the level of the ring of 3□ adductors, rises through the Hunter canal and crosses the sartorius muscle. Its origin is outside of the superficial femoral artery, at the rear in mid-thigh and within the crural ring. It receives the deep femoral vein, with the same name as the artery, 6 cm from the arch.

Above the crural arch, the external iliac vein follows on from the common femoral vein before joining the internal iliac vein to form the common iliac vein. Where these two common (or primitive) iliac veins meet is the origin of the inferior vena cava.

3.3. Histology

The venous system begins at the level of micro-circulation. The arteries are extended by arterioles and finally by meta-arterioles. From these run the capillaries that branch into microvenule and in parallel the artero-venous anastomoses.

The post-capillary microvenule have a diameter of 10 to 30 µm. Their walls are comprised of endothelial cells lying on a basal membrane encased in a layer composed of pericytic cells and fibroblasts. This layer increases as it moves away from the capillaries. The post-capillary microvenule converge into collector venule with a diameter of 30 to 50 µm. Their walls are made up of smooth muscle cells. The collector venule join up with the veins.

The capillary flow is regulated by a dual system: the pre-capillary sphincters and Masson's neurovascular glomus (which forms part of the neuro-vegetative system).

Varicosities occur in the superficial dermis. There are no vessels in the epidermis. The saphenous veins and the largest varicose veins are located in the deep dermis, especially the hypodermis, in contact with the adipous lobules.

3.3.1. The Vein Walls

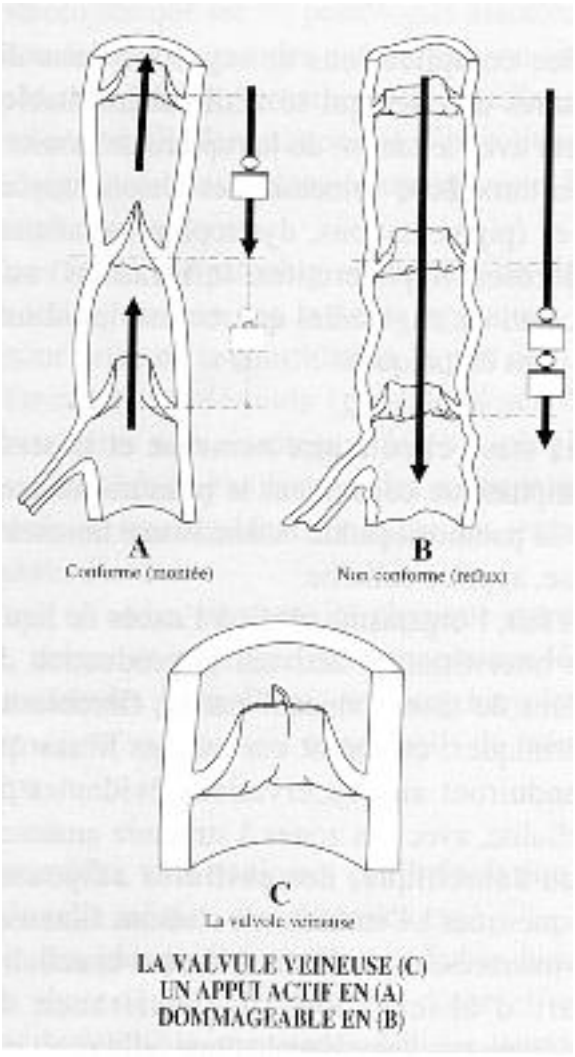
They are composed of three tunics:

- The Intima or internal tunic: Composed of a vascular endothelium - a sub-endothelial layer of mucoglycoproteins of conjunctive tissue and cells, this is the seat of the endothelial cell. The latter is in constant communication with the elements of the blood and its response to hypoxia is the prime mover in the biochemical cascade that leads to venous incompetence.

- The Media or middle tunic composed of smooth muscle fibres and an elastic conjunctive structure.

- The Adventitia or external tunic; the vasa vasorum, vessels that nourish the vein walls, are located in this conjunctive tissue. They are accompanied by lymphatic vessels and sympathetic nerve endings. These vasa vasorum carry oxygen and nutrients to the vein wall and a lack of perfusion can give rise to hypoxia of the median layer leading to a structural alteration of the vein wall.

3.3.2. The Valves



A semilunar flap of endothelial tissue, the main function of which is to segment the blood vessels and above all to prevent blood reflux.

This flap thins the vein wall near the valve thereby making it more fragile.

The valves have passive mobility in the lumen of the vein. They are more numerous in the deep veins.

If they function correctly, they close totally when the venous pressure downstream is greater than upstream.

3.3.3. The vascularisation and innervation of the vein wall.

The vasa vasorum are responsible for vascularisation of the vein wall. These are fine vessels that come from the adjacent arteries.

The alpha-adrenergic sympathetic nervous system is responsible for the contraction of the vein wall and therefore for vasoconstriction.

3.4. Physiology

The physiology of return circulation is complex and still involves many unknowns. It has to perform several functions:

- returning blood to the right side of the heart
- cutaneous thermoregulation
- regulation of the cardiac flow
- reservoir of blood mass

It has to deal with difficult conditions that have been known for a long time. Bipedality aggravates the hydrostatic and hydrodynamic factors that it has to combat, resulting in venous hyperpressure.

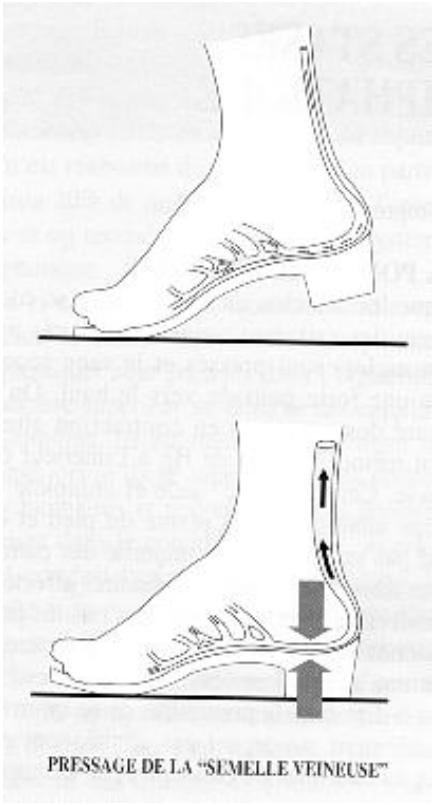
This venous hyperpressure, responsible for micro-circulatory problems, is the key factor in venous ailments and their potential for development.
Gradual functional adaptation over thousands of years, with a unique venous blood propulsion system deals with the main problems posed by gravity. However, the effectiveness of these adaptation mechanisms is being challenged by modern living conditions.

Even though these physiological blood return mechanisms are partly known, their respective importance has not yet been properly defined.

Many factors are involved in venous dynamics.

3.4.1. The muscular and articular pump

The contraction of the calf muscles during effort compresses the veins and favours the flow of blood towards the heart. The effectiveness of this contraction depends a great deal on the articular condition of the ankle and to a lesser degree of the knee.


PRESSAGE DE LA "SEMELLE VEINEUSE"

Squeezing the plantar venous sole allows the blood to flow to the deep venous trunks and the saphenous veins. Around 30 ml of blood is expelled each time the foot comes into contact with the ground.

The contraction of the calf muscles: the blood mass is ejected towards the heart by the compression of the muscular veins and deep veins. The deep vein valves prevent reflux upstream and towards the superficial venous network. The non-extensible aponeuroses limit the dilation of the calf muscles. Naturally, the effectiveness of this muscular pump depends on the development of this muscular mass (especially the gemellary and solear muscles).

It will be much larger in sporting than sedentary persons, in men than in women.

The sural venous muscular pump, a veritable peripheral pump, reduces the distal venous pressure by 40% and the blood sequestered by orthostatism by 200 ml. In an immobile standing position, the venous pressure is 90 mm Hg after 30 seconds. The hemodynamic repercussion is rapidly felt upstream with an increase in capillary pressure and the appearance of an edema.

Finally an increase in adipose tissue in the leg significantly increases the work of the muscular pump (see the study by Dr Chardonneau of heaviness of the legs, *revue de phlebology* 1999)

The articular condition: each articular movement pushes venous blood towards the heart. It follows that articular amplitude is a key factor in the expulsion of blood.

3.4.2. The diaphragm pump

The rhythm of venous blood return is controlled by respiration. The further we go into the large veins (popliteal - femoral - iliac), the more this phased movement is felt. A Doppler reading easily confirms this, in the decubitus position.

During inspiration, the diaphragm is drawn lower into the abdominal cavity as the volume of the thorax increases. Thoracic pressure falls and the intra-abdominal pressure increases. This effect tends to squeeze the inferior vena cava and to propel its contents towards the thorax. The venous valves prevent any reflux towards the inferior members.

During expiration we find that the diaphragm rising into the thoracic cage is responsible for an influx of venous blood into the inferior members of the abdominal cavity.

3.4.3. The tonus of the Vein Wall

This venous tonus depends on the sympathetic nervous system. The release of certain chemical substances following stimulation of the adrenergic nerves results in contraction of the vein wall. These vasomotor reflexes are especially common in the superficial veins. They do not exist for the muscular veins.

Orthostatism, cold, stress, deep respiration, physical effort and hyperventilation increase the venous tonus.

On the contrary, rest in the decubitus position, heat and the absorption of alcohol reduce it.

Certain medicinal products reduce the venous tonus: B-blockers, nitroglycerine, nitrate derivatives, theophylline and barbiturates.

Finally, it is increased by non-compensated cardiac insufficiency.

3.4.4. Aponeuroses of the Legs

Their role is certainly underestimated.

Their resistance to variations in volume and pressure increases the effectiveness of the muscular pump. It is not simply a passive envelope, but participates actively to the ejection of blood from the deep veins.

3.4.5. Residual Arterial Pressure

This is what remains of the systolic propulsive force of the left ventricle after arterial flow to the capillaries. It plays only a moderate role.

3.4.6. Arterial Pulsatility

The rhythm of the venous flow is controlled by the satellite artery that exercises pressure on it. This pressure propels the venous blood in the opposite direction to the arterial blood. However, it only makes a modest contribution.

3.4.7. Cardiac Aspiration

A moderate intra-auricular systolic suction effect is produced by the downward traction of the tricuspid and mitral valves. This mechanism is particularly reduced in the case of arrhythmia.

3.5. General information of Venous Dynamics

The anti-reflux role of the valves is dependent on the integrity of the flaps (2 or 3) that float in the lumen of the vein. They tolerate pressure in excess of 200 mm Hg. The closing speed of the valves is less than 0.5 seconds in the event of rapid reflux.

- ***Parietal Distensibility***

The peripheral vein walls contain little smooth muscle tissue and are fine. They are easily distended.

They become larger with age. This distensibility of the vein wall depends on the level of progesterone serum.

- ***Venous capacity***

The lumen diameter of the vein is 20 µm for venule, 5 mm for average peripheral veins, and 3 cm for the vena cava

Venous compliance is 24 times greater than for the corresponding artery.

The veins are capacious vessels; 64% of the blood volume flows through the veins, 1/3 of it in the major veins and the blood reservoirs (spleen - liver).

- ***Veinous Pressure***

In decubitus: the hydrostatic venous pressure is 20 mm Hg. In the case of existing varicosity, it varies between 40 and 70 mm hg, and in the case of a post-thrombotic syndrome it oscillates between 50 and 85. Venous blood return in the supine position is characterised by a low-pressure peripheral and a shallow pressure gradient: pressure at the ankle of 12 to 18 mm Hg and filling pressure of the right auricle -2 to 10 mm Hg. Hence the moderate suction effect created by the heart.

In the sitting position: venous pressure at the ankle is 56 mm Hg.

In orthostatism: in an immobile standing position the pressure is 85 mm Hg for an average-sized adult. It increases by 0.8 mm Hg per additional centimetre of height. When taking up a standing position, the blood volume in the inferior members increases by 300 ml, which is responsible for a transient diminution of the cardio-respiratory blood volume and the systolic volume.

When walking - contraction phase: It varies between 85 and 95 mm Hg in the medial malleolar saphenous vein just before the heel leaves the ground and falls to 70 mm Hg when the foot is lifted.

Release phase: the leg musculature relaxes and then the crural musculature contracts. When the heel touches the ground and rests, the pressure falls to 46 mm Hg.

The drop in venous pressure at the ankle to below the hydrostatic pressure occurs after 3 to 12 paces, independently of the walking speed.

- ***Speed of Veinous Blood Circulation***

The speed of the venous blood flow in the vena cava is 10 cm/s. It varies depending on the position of the subject. In dorsal decubitus the speed of circulation in the legs is 2 cm/s. It falls by 40% in orthostatism.
It increases by 20% when walking, 60% during gymnastic exercise of the toes, 80% when wearing an elastic restraint, 90% during gymnastic exercise of the feet, 150% when the end of the bed is raised by 20 %, 270% when the subject is lying down with the legs raised vertically, and 340% peddling in the same position

3.6. Varicosities

Varicosities fall within the two worlds of phlebology and aesthetics.

Modern phlebology is based on their co-existence. These are no capillaries, but permanent dilations of the intradermal microvenule with a diameter that varies between 0.1 and 1 mm.

They differ in appearance:

- Isolated in small branches
- Diffuse spider's webs
- In the form of hairlines.

They mostly affect certain areas: internal and external knee - thigh - internal ankle - external leg. They may be spontaneous or secondary and occur after stripping or sclerosis, in which case they are referred to as matting.

Their colour varies from bright red to dark blue and the diameter depends not only on the depth, but also on the oxyhemoglobin content.

They are covered by various medical disciplines: phlebology - angiology - dermatology - aesthetic medicine - plastic surgery - vascular surgery - internal medicine.

3.6.1. Prevalence

It is difficult to broach the subject of ***varicosities*** without referring to their prevalence. They are an extremely frequent reason for consultation.

Between January and September 1995, Professor CATTALINA, a specialist in occupational medicine, and SOFRES medical, studied 1,823 women working in four health sectors; operating theatres, laundries, crèches and secretariats. An analysis of the results showed that the time spent in the job was the leading factor affecting the seriousness of the ailment. Then, in decreasing order, the number of pregnancies and obesity. A high temperature in the workplace and carrying heavy weights seem to be aggravating factors for venous ailments. Heredity does not seem to affect the severity of the problem. Do the genes play a role in the expression of the ailment? Finally, 68% of women working in the operating theatre had varicosities compared with 51 to 54% in the other sectors.

The SUVIMAX study in 1999: 3,065 persons who were monitored for a period of four years showed that 33% of women were diagnosed with chronic venous insufficiency and 28%

declared that they had symptoms indicating venous insufficiency without a medical diagnosis.

The NIH study in the United States of 600 employees at the University of South California found that varicosities affect 67% of the total population, and varicose veins 25%. Varicosities, which increase with age, vary between the sexes (women 83% - men 51%) and according to racial group: higher frequency amongst Caucasians and lower amongst Blacks. Varicose veins are twice as frequent in women as in men, with no ethnic difference. Venous pathologies affect half of the adult population and 3/4 of the elderly, particularly women.

A survey conducted by the MEDIA Institute showed that 70% of first consultations in a phlebology practice were because of varicosities.

An INSEE study in 1996 stated that 71% of menopausal patients had varicosities.

3.6.2. Etiology

Even though the physiopathology remains partially hypothetical, we can identify four main types:

- ***Red varicosities***

They merge into marks or zones.

They are fine and superficial.

One particular form should be noted: the "red sock syndrome". This affects women over the age of 45 with very fine, very superficial red varicosities on the legs, ankles and the back of the foot. No varicose veins are found.

The difficulty of catheterising these micro-vessels limits the therapeutic options. Recidivism frequently occurs

- ***Matting***

Small angiomatous, circumscribed and congestive, they are secondary to an aggression, an external or iatrogenic traumatism (contusion) caused by :

- Stripping
- From traumatising surgery
- From a major hematoma
- From the persistence of an accessory saphenous vein or an incontinent perforator
- From phlebectomy: generally if the varicose vein is left in place
- From sclerosis: sclerosis nearby with an excessive concentration or too much injected

An area predisposed to varicosity is probable. Biological or hemorheological factors could play a role.

Varicosities fed by drainage venule

Major category. An Australian study by Thibault showed that 25% of symptomatic varicosities were associated with major sources of valvulary venous insufficiency. These varicosities are often found in groups.

Hemodynamic Reflux

Reflux is responsible for these varicosities, which appear after the superficial venous network is subjected to pressure. From a physiopathological standpoint, the transmission of pressure from the reticular veins to the venule probably results in their dilation and transforms them into telangiectasis and venulectasis.

Thanks to micro-phlebography, it has been possible to determine the origin of the reflux.

In 30% of cases we find the deep venous network isolated.
In 20% the superficial venous network.
And in 50% of cases, both networks.

Finding these reticular drainage veins is not always easy. It requires careful examination. Clinical examination must be able to find a reticular venule. The inferior member should be observed in the centripetal direction.

It is also possible to use cartography of the drainage zones to find the root causes of telangiectases.
The different zones are:

- medial saphenous vein
- external saphenous vein
- anterior crural saphenous vein
- superficial circumflex iliac vein
- saphenous vein medial accessory
- The "lateral venous system under the dermis" described by Albanese .....

In difficult cases ***transillumination*** can be helpful.

Varicosities with cellulite

Cellulite, an inexhaustible subject in the popular press, is much less obtrusive in medical publications. Its physiopathology and definition have long been a source of controversy. Currently it seems reasonable to reserve the term cellulite exclusively for the disfigurement that affects our contemporaries in a variety of ways.

This is a lipodystrophy, in other words an increase in the number or volume of adipocytes. They are found in the superficial part of the hypodermis. Cellulite is dependent on vascular, hormonal, genetic and nutritional factors. The vascular factor, i.e. stasis, leads to water retention and contributes to maintaining and aggravating the cellulite.

On the contrary, adipocyte hypertrophy disrupts veno-lymphatic return and the compression by external pressure of the superficial venous system creates upstream hyperpressure with dilation of the microvenule and the appearance of varicosities. These varicosities are often isolated.

3.7. Clinical examination

It draws on the knowledge and experience of the doctor. It expresses the nobility of our art. It is irreplaceable.

The aim of clinical examination is:

- To assess the overall condition of the limb:
- Physical examination of the leg: shape - appearance - oedema - varicose veins - cellulite - signs of cutaneous distress.
- To identify negative factors who are generated by return of the varicose veins and try to prevent the return.

3.7.1. Clinical History

Reasons for consultation

Aesthetic

90% of consultations.

The beauty of the legs is a major element of the feminine aesthetic and no phlebological lesion is acceptable from an aesthetic point of view.

Prevention

Since venous ailments are reputed to be hereditary, requests for consultation as soon as the first varicosities appear in a person with family antecedents are far from rare. Is this well founded? The CEAP (international classification of venous disease) considers it to be the first stage of venous insufficiency.

Do these varicosities lay the foundation for varicose veins? Nothing could be less certain, as this hypothesis is not confirmed by any study.

Identifying Aggravating Factors (on which no action can be taken)

The number of pregnancies

The prevalence of varicose disease is proportional to the number of pregnancies. Therefore, after the first pregnancy, the risk would be 23%, with 27% for a 2nd and 3rd pregnancy and 31% for the 4th. Finally, pregnancy very much favours the appearance of varicosities (even though there is a decrease spontaneously post-partum).

Heredity

There is no denying the existence of a hereditary factor in venous insufficiency. However, its preponderant role has been challenged. Indeed, the incidence of venous insufficiency increases in industrialised countries (Europe, North America, Japan), whilst the birth rate is constantly falling. In parallel, certain populations (Black Africa, New Guinea, Polynesia) that are free from the disease develop the disease when they move to the industrialised countries.

Lifestyle seems to be a more important factor than heredity in the occurrence of venous disease.

Finally, K. Hubner, following a study of the unilateral and bilateral distribution of varicose veins and varicosities in 12,313 patients, confirms that from a genetic standpoint saphenous varicose veins and varicosities are two different entities.

Traumatism

Contusion, accident, hot wax hair removal, massage gloves, treatment of cellulite using certain depression-massage appliances, pressure therapy using high pressure multi-compartment sleeves and balneotherapy with underwater jets are aggravating factors.

Veinous therapies

Saphenous vein stripping, Chiva technique, phlebectomy , sclerotherapy, laser, electrocoagulation, micro-phlebectomy … are also aggravating factors.

Identifying Aggravating Factors (on which action can be taken)

Weight

The Framingham study showed a positive correlation between high body mass and the risk of varicose veins. There is an increase of 29 to 39% in persons who are overweight. This is mainly a risk factor of cutaneous complication in the varicose patient.

Height

The correlation between height and the presence of varicose veins has been shown to be significant in several studies.

Aggravating sports

Although physical activity is highly recommended to encourage good venous hemodynamics, the practice of certain sports can prove harmful. For all sports, any excessive training is harmful for the venous system. It results in venous hyperdistensibility with the risk of parietal and valvular alteration, followed by venous hyperpressure and hypoxia.

Working position

There is unquestionably a link between a standing or sitting working position and the prevalence of varicose veins. It depends on the number of hours a day of sedentary activity and the time spent in the job

Others factors (unproven)

Restrictive closing – Constipation.

Hormonal Pathology

Studies give conflicting results and it appears that the oestroprogestative hormones favour varicosities and reticular venule, but reduce the risk of the appearance of truncular varicose veins.

3.7.2. Clinical procedure

How to examine a leg?

Observation and palpation are the two main elements of leg examination:

In orthostatism: Anterior and posterior vertical position; greek statue position; fencing position.

In decubitus : Anterior and posterior and lateral

Observe in the centripetal direction (foot-thigh) and pull on the skin in order to flatten it.

Examination in the centripetal direction, smoothing the skin with both hands, is used to find a feeder venule. Palpation may reveal a small cutaneous depression indicating the presence of a hypodermic vein. Search for the clinical barriers to venous and lymphatic return.

Plantar arches

The negative impact of static plantar ailments on venous insufficiency is real enough and we therefore need to combat high arches, flat feet and valgus foot deformity.

Condition of the ankle and knee joints

The ankle articulation plays an important role in the calf muscular pump and any alteration in the mobility of the ankle joint can lead to the appearance of venous hyperpressure of the leg even in young patients. The same phenomenon exists to a lesser degree at the knee.

Condition of the calf and abdominal muscles

These two muscle groups play a primordial role. Any organic or functional deficit has significant repercussions on venous return.

Presence of cellulite

Cellulite is a lipodystrophy composed of three elements:

- adiposis
- stasis
- fibrosis.

The hypertrophy of the adipose lobules clearly disrupts the venous and lymphatic return, resulting in a pressure increase in the venous sector.

When it affects exclusively or mainly the legs, it is commonly referred to by the inadequate term of lipoedema. Diagnosis of lipoedema is based on:

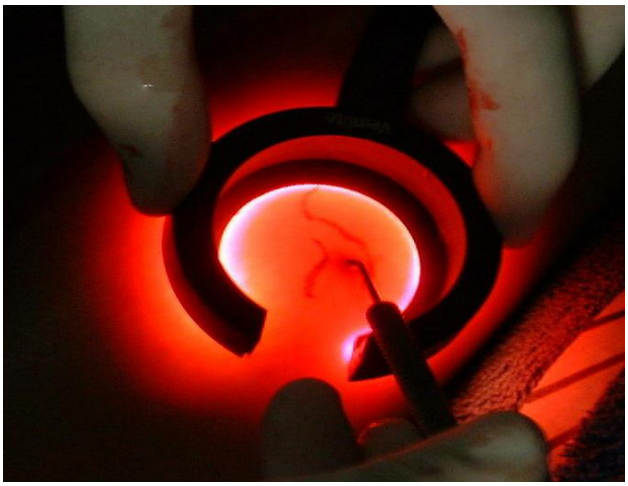
- a rather light flexible edema
- its bilateral character
- absence of Stemmer's sign
- Chardonneau's sign (appearance of an internal retromalleolar adipose groove when the skin is pinched)
- characteristic of cellulitic infiltration in the ankle.

Finding a drainage venule

The physical examination must be meticulous and patient.

For varices mainly in orthostatism, use palpation to get more elastic cutaneous. Starting with the course of the saphenous veins who run vertically, and for the other superficial veins who run horizontally.

For the venule by inspection in decubit. Examine in the centripetal direction of the venous flow (foot - thigh) from different angles, with different lighting if possible, drawing and smoothing the skin with both hands.



Transillumination has become almost indispensable for dealing with these feeder veins.

It uses a cold light source and fibre optic cable. The end of the fibre comes into direct contact with the skin. The light passing through the skin is reflected by the fascia superficialis (deep dermis) and the veins appear as Chinese shadows. It can show the veins located on the deep side of the dermis. A tortuous or looped appearance is a sign of a pathology.

4. THE THERMOCOAGULATION

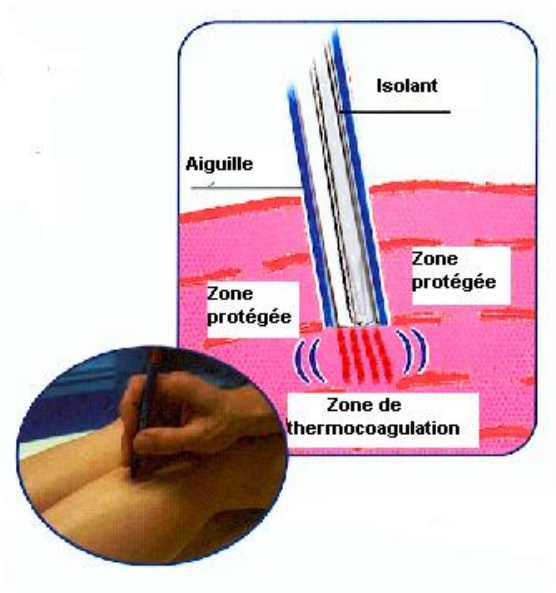
A PRACTICAL GUIDE TO THE TREATMENT OF VARICOSITIES by Dr. Jean Marc CHARDONNEAU

The therapeutic approach to varicose disease is relatively well developed and today, whatever the type of varix, its location or diameter, it can almost certainly be eradicated. The same does not apply to varicosities. This is bitterly disappointing, knowing that they represent more than 70% of the reasons for phlebology consultations.

The traditional therapies vary in their effectiveness. Microsclerosis, the reference technique, even in the hands of experts can only hope to achieve good results in 65% of cases. The laser technique still has to prove itself and for the moment few studies demonstrate its usefulness in the arsenal of therapies for varicosities.

We therefore thought it would be interesting to study a new physical procedure called **Thermocoagulation.**

4.1. Principe



The principle is based on the use of a very high frequency wave (4 million Hertz), which causes a thermal lesion. This wave varies slightly over time, allowing progressive burning of the tissues whilst avoiding their carbonisation.

These modifications allow targeted and effective use, limiting the risk of cutaneous lesions.

It is necessary to distinguish between electrocoagulation and thermocoagulation.

Physiologically: electrocoagulation ionises NaOH, separating the Na+ and OH-, and is therefore a chemical burn.

Thermocoagulation, by heating the atoms, creates a thermal burn.

Clinically: Electrocoagulation has not always given satisfactory results. Firstly, it can cause depressed scars that are frequently achromatic, and second, the pain is difficult to bear.

Although thermocoagulation is certainly not painless, in general it is well tolerated. Finally, it is never responsible for serious cutaneous lesions.

Lesions from thermocoagulation are influenced by:

- the power of the wave emitted
- the duration of application of the wave
- the modulation of the wave.

4.2. Equipment

The appliance is comprised of a generator with a programmer linked to a pedal and to a needle holder.

4.3. Technique

4.3.1 Needle treatment

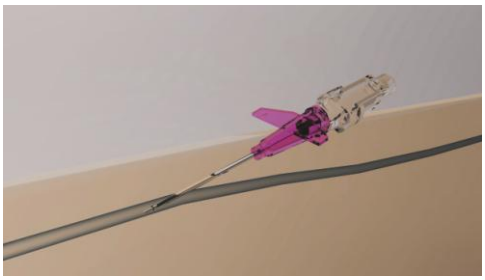
The technique is simple but requires absolute rigour.

It is strongly recommended to follow the seven golden rules.

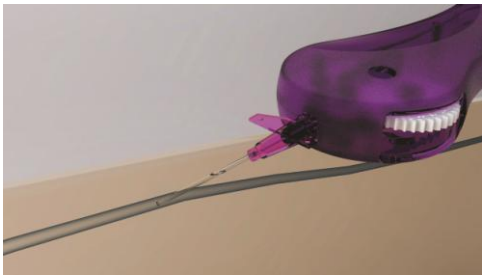
1. Insert the needle perpendicular to the skin
2. The zone to be treated must be horizontal
3. Use a magnifying glass to avoid inserting the needle outside of the vessel
4. Clean the needle regularly with a sterile compress
5. Pulse every 2-3 mm
6. Work at a very superficial level
7. Use the appropriate diameter Ballet needles

4.3.2 Perforating-, Collateral- and Reticular vein treatment

1. Introduce the needle with the guide into the vein.

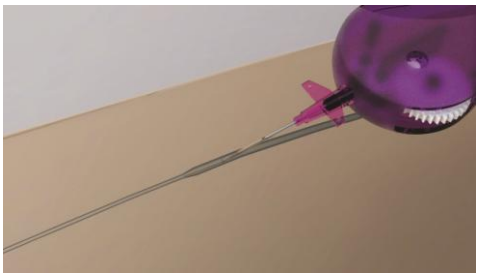


2. Take the needle out and leave the guide in the vein. (You can see backflow if you are in the vein)



3. Connect the sterilized handset to the guide

4. Slide the catheter into the vein by turning the wheel of the handset



5. Retract the catheter while holding down the footswitch to invoke RF signal

6. When you are at the end of the vein. Take the needle and the guide out.

4.3.3 Saphena Magna treatment

1. Insert the Argon Percutaneous 6 frenge introduction needle into the Saphena Magna
2. Take the needle out en leave the guide in the Saphena Magna
3. Insert the CR45i catheter with a 0,5 cm tip into to Saphena Magna
4. Retract the CR45i catheter every 0,5 cm after 3 beeps while you press down the footswitch to invoke RF signal
5. Retract the CR45i catheter slowly out of the Saphena Magna.
6. Take the Argon Percutaneous needle out, the treatment has been done.

4.4. Clinical study

THERMO COAGULATION OF THE VARICOSITES: 6 YEARS OF RETREAT
by Dr. Jean Marc CHARDONNEAU

The study concerned 400 patients from 25 to 70 years of age with an average age of 43. Each patient was treated in 4 to 5 sessions.

- ***Protocole***

- The sessions lasts for 10 to 15 minutes
- The number of pulses varies between 100 to 300
- and the period between two sessions is three weeks.
- No compression or hemostatic dressing is used.

- ***Results***

Instantaneous disappearance of the varicosity

Small erythematous papule during the minutes that follow

Scratched appearance for a few days to a few weeks followed by total disappearance.

- ***Complications – Incidents***

- Very few secondary effects were observed.
- Very rare erythism and transient accentuation of the varicosity.
- Exceptional pigmentation from overdose, An overdose could come from the following events:
  - Pulses too close together
  - Excessive duration of the pulse (0.8)
  - Power too high
  - Several passages in the same location)
- Lack of results due to technical faults (pulse too deep or lateral, unsuitable needle)

- ***Patient experiences***

- No severe pain
- Easier to bear than microsclerosis
- Comfort: absence of dressing - absence of ecchymosis

- No post-treatment irritation or pain
- Treatment possible all year round
- Safe

4.5. Contra-indications

- Allergy to nickel and chromium (use a gold needle)
- Pacemaker
- Cutaneous infection

4.6. Advantage of Thermo coagulation

- easy to use
- instantaneous disappearance
- allergies exceptional
- no durable pigmentation
- no necrosis
- speed of treatment (session lasts a maximum of 10 to 15 minutes). For 300 to 400 pulses, in a single session we eradicate 80 to 100 cm of varicosities.
- highly effective:
- on all types of varicosities (small varicosities)
- in all locations
- on zones inaccessible to microsclerosis (< to 0.3 mm).
- on zones of the foot.
- can be used on all types of skin.

4.7. Conclusion – Discussion

Microsclerosis is currently the reference treatment for varicosities, but it does seem likely that phlebologists and other practitioners interested in this type of aesthetic damage will soon give preference to thermo coagulation.

Thermo coagulation, without the least danger, treats the same symptoms as microsclerosis or laser therapy, but with superior results.

This therapy has been in use for 30 months. We have observed no recidivism in the patients monitored. It is very difficult to find parallel studies that demonstrate the effectiveness of microsclerosis.

Secondary effects are virtually non-existent if we follow the seven golden rules.

Failures are rare.

5. TREATMENT PROTOCOLS

A PRACTICAL GUIDE TO THE TREATMENT OF VARICOSITIES by Dr. Jean Marc CHARDONNEAU

5.1. Type of Needles

For easy penetration, use Ballet needles.
The size varies according to the diameter of the varicosities to be treated

☞ - K3i 0.075 mm for very fine varicosities of less than 0.3 mm
☞ - K6i 0.150 mm for varicosities of more than 0.3 mm

5.2. Adjusting the parameters

There are two adjustable parameters: the power of the wave and the emission duration. In general:

- intensity: 5 – 8 watt
- duration of emission: 0.2 s – 0.3 s

Systematic test before each pulse

Before sending the pulse, you must find the correct needle position by pressing on the varicosity with the needle until a small thread of varicosity disappears, confirming that you are properly positioned on the varicosity. The gentle pressure of the needle should make the varicosity disappear. At this moment, insert the needle very gently (still superficial) and send the pulse.

Verification of effectiveness

Immediately :
- pull the skin well after treatment with both hands to see, using the magnifying-glass, that the varicosity has disappeared
- if the pulse is too lateral, the varicosity will reappear
- disappearance in itself is not a sufficient condition (because it is masked by the oedema) for the success of the treatment, but it is a necessary condition.

From day8 until day 15 :

- repeat the inspection.
- the space between the pulses must be pink and empty, indicating the disappearance of the varicosity.

5.3. Pragmatic approach

Practical detail that may be used as a guide: 0.055 mm is the smallest diameter needle used in phlebology (13 x 0.3) - if the vessel can be catheterised it is more than 0.3 mm

- ***Stage 1***

- red and blue varicosities < 0.3 mm (non catheterisable)
- isolated
- external leg of ankle
- needle K3i
- power setting 5 – 8 watt
- pulse time 0.2 – 0.3 s

Remain at this stage during one month normally.
The result is 100% disappearance.
If certain varicosities have not disappeared, check that the effects of thermo coagulation are not found alongside the varicosity.

- ***Stage 2***

- varicosities < 0.3 located in the knees and thighs
- parameters identical to the first stage

During 15 days only do this and await the result.
This procedure is a little more delicate as these varicosities are often fed by a venule.
However, the correct technique should lead to a very positive result approaching 100%.

- ***Stage 3***

After six weeks of thermo coagulation apprenticeship, go on to stage 3
- isolated varicosities > 0.3 and < 0.6 mm; use needle K6i
- very good result

- ***Stage 4***

Varicosities > 0.3 grouped and fed by a reflux
More difficult to tackle - for the best result, it is preferable to treat the reflux first by using microsclerosis for example.

5.4. Evolution of the treatment

- ***Normal evolution of the treatment***

- D 0: instantaneous disappearance of the varicosity with the appearance of an erythematous micro-oedema
- D 8: appearance of very fine micro-scabs corresponding to the pulse points.
- D 30: total disappearance

- ***Abnormal evolution of the treatment***

- Disappearance of the oedema followed by reappearance of the varicosity over the days that follow.

- The varicosity, in reality, has not been treated correctly and the oedema masked the result.
- Pigmentation (always disappears)
- Ochre marks of varying shades appearing a few days, or even a few weeks, after the treatment. These are associated with the use of non-insulated needles (more rarely) or a technical fault (the non-insulated part of the needle, the last millimetre, is in contact with the skin), often following an overdose.
- Transparent appearance of the skin (burn) - pulse too superficial
- Dotted appearance: some of the varicosities were correctly treated (wait one month and then treat the remaining part).

How to avoid this problems

Lack of results

Strictly follow the protocol and the delay between each stage. This is often caused by a lateral insertion, alongside the varicosity. The great majority of cases are due to a lateral pulse alongside the vessel. You must take time, carry out the tests, making sure you are in the vessel, send the pulse and use a magnifying-glass.

- By small varicose veins, the capacity can be increased up to 12 watt, to ensure that the vein is closed.
- If the varicose vein has a larger diameter, increase the power and the duration of the emission to 0.5 seconds.

5.5. Specificity of rosacea

The rosacea are a chronic and evolutionary skin trouble causing ignition and redness in the face. The cheeks and the nose are usually the first to take a red dye, follow-ups of the face and chin.

The blotches can touch any old person from 20 to 70 years, but the adults from 30 to 50 years having the clear dye and whose skin tends to redden easily are more often affected. The women are more prone there than the men but the latter are more inclined to develop a *rhinophyma*, a disorder which is characterized by a nose red, swollen and embossed and which is secondary with untreated blotches. It requires a surgical correction. Approximately 15 % of the population is affected.

This type of acnea is distinguished obviously from the common acne. In the case of the blotches, redness and the papules also appear in a cyclic way, but not in black spots or white buttons. The lesions are rather red, hard and of small size.

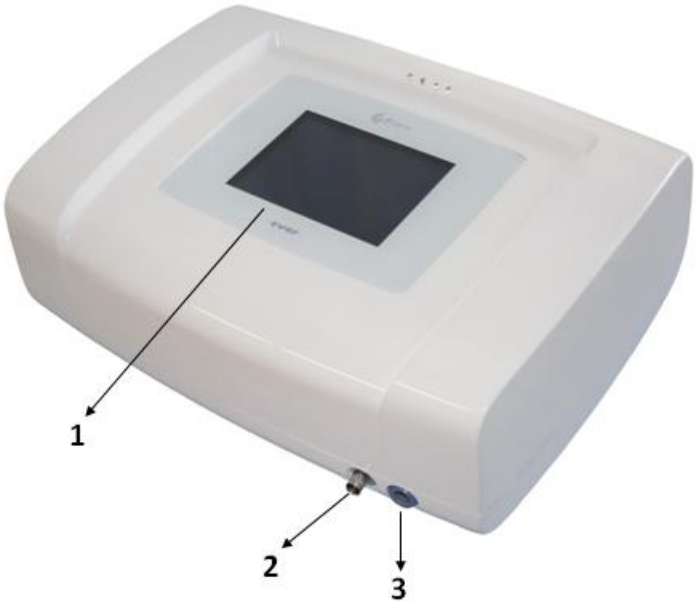
Adjusting the parameters

- power 5 – 8 watt
- pulse time 0.2 s – 0.3 s
- maximum number of pulses 300 / session
- frequency of sessions: every 3 weeks

For a face 3 to 4 sessions are required.
Control after 8 weeks with maintenance once a year.

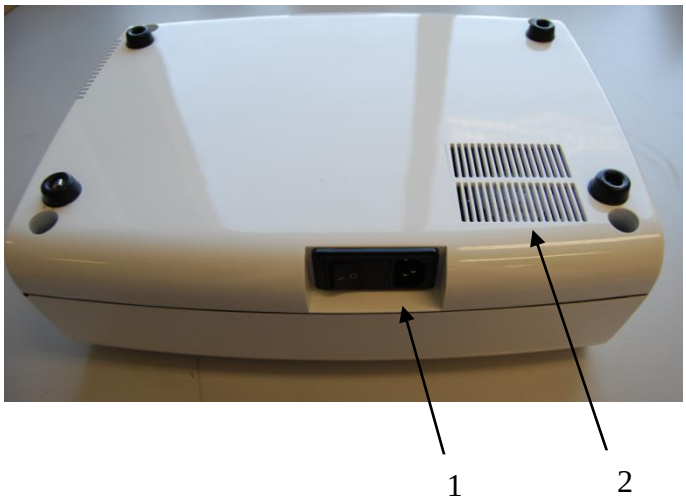
6. DESCRIPTION OF THE APPARATUS AND THE ACCESSORIES

6.1. Front face of the EVRF



1. Display with touch screen
2. Connexion for the needle- holder pen or catheter (silver)
3. Connexion for the treadle (blue)

6.2. Bottom side of the EVRF



1. Main power supply + fuse holder + ON/OFF switch
2. Cooling fan

6.3. Accessories

The accessories of the EVRF are the following:

6.3.1. Foot switch

The footswitch permits to activate the high frequency impulses.

It connects the blue connector with the EVRF.

6.3.2. Needle-holder pen (with cable of connexion)

Linked to the apparatus, it permits to transmit the high frequency impulses through the needle.

6.3.3. Needles

The apparatus is delivered with a set of F Care needles.

The needles are in nickel, type : “F CARE K3i” (0,075 mm) and “F CARE K6i” (0,150 mm). They must imperatively have the CE mark imposed by the Directive 93/42/CEE.

6.3.4 Handset

The apparatus is delivered with a F Care handset including cable of connexion.

The handset will be used to coagulate the veins from the inside out. The catheter, which is scrolled out of the handset, can be inserted into the vein for a maximum of 8-10cm.

6.3.5 Insertion needles

The insertion needles are used to make the initial insertion in the vein. After the insertion has been done you pull out the needle and leave the flexible part in the vein. This flexible part will guide the catheter of the handset in the vein.

7. USE

The use of the EVRF is very easy.

- Connect the needle-holder pen or handset to the apparatus (red plug), thanks to the cable provided on this aim.
- Connect the foot switch to the apparatus (blue plug).
- Switch on the apparatus, the welcome screen appears. Afterwards the mode selection screen is shown.

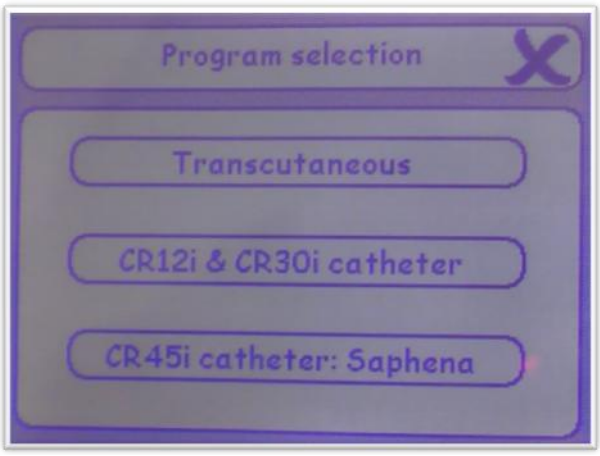
The welcome screen is shown for 3 seconds.

Afterwards the mode selection screen is shown.

In this menu you have the option to choose between 3 modes:
- Transcutaneous,
- Endovenous: CR12i and CR30i catheter
- Endovenous: CR45i catheter: Saphena.

Changing the selection can be done by touching the button

By touching ✖ you go to the settings screen.



7.1 Configuration of the EVRF

After touching the ✘ button you end up in the settings screen.

In this screen you have the option to alter 2 settings: language, and screen contrast.

By touching one of the buttons you will be able to change the selected option.

By touching ✘ you go back to the mode selection screen.

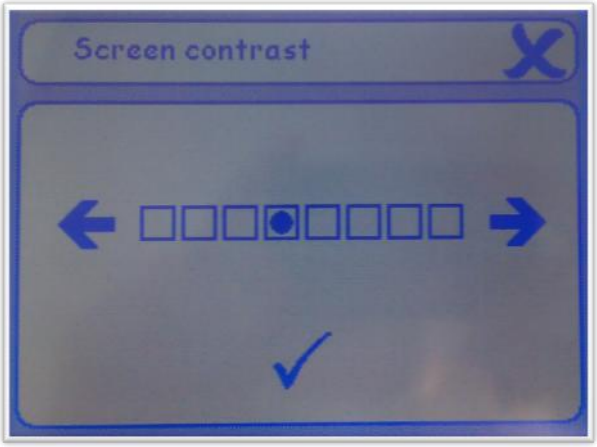
7.1.2. Language settings

If the "language setting" option was chosen we end up in the following screen.

Several languages can be selected: French – English -Italian – Spanish - Portuguese - Norwegian – Swedish - Deutsch - Dutch.

Choose the desired language with the up/down arrows and touch the language you wish. Touch ✘ to cancel and return to the settings selection.

7.1.3. Screen contrast



If "screen contrast" was chosen we enter the screen to change the contrast.

Choose the desired contrast settings with the left/right arrows and touch ✓ to accept. Touch ✘ to cancel and return to the mode selection

7.2 Use of the EVRF

When we are on the mode selection screen we have the option to choose between 3 different modes: Transcutaneous, Endovenous with the CR12i & CR30i catheter and CR45i catheter: Saphena.

7.2.1. Endovenous treatment

CR12i & CR30i catheter

In this screen we have the option to change the wave power from 1 watt to 16 watt.

The wave power will be decreased when you touch or it can be increased by touching

Joule :
This is the sum of the amount of energy generated over a period of time.
The Joule is the multiplication of watt X seconds.

For example: when setting the EVRF at 15 watt, after 4 seconds you have 15 x 4 = 60 joules.

The EVRF will give a sound beep every two seconds, so you know that every beep, you have generated 2 times the watt that was set on the EVRF. This is the amount of joule that the EVRF generated.

The Pulse width cannot be changed since this is continuous mode.

If the machine is in “ON” mode and you push the foot switch, the wave will remain on the output for as long as you keep the foot switch pushed.

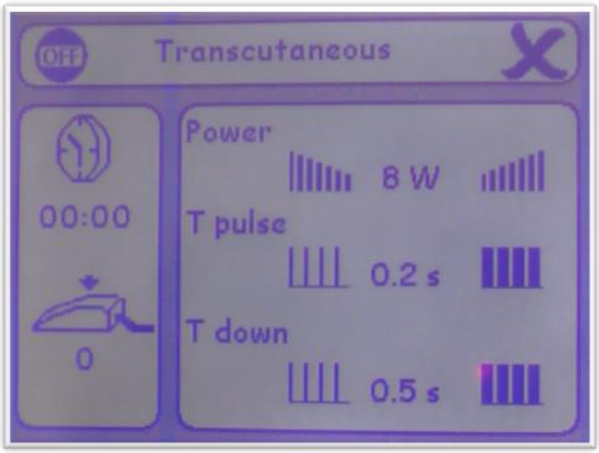
CR45i catheter: Saphena

In this screen we have the option to change the wave power from 16 watt to 25 watt.
The wave power will be decreased when you touch or it can be increased by touching

Joule :
This is the sum of the amount of energy generated over a period of time.
The Joule is the multiplication of watt x seconds.

7.2.2. Transcutaneous treatment

This screen indicates:



- The value of the standard power which is, for the Variculas, 8 watt. We can increase or decrease this power.
- The duration of the impulse width (T pulse). We can decrease or increase this time.
- The time between 2 pulses (T down). This time can be decreased by touching or increased by touching
- On the left we have a clock which will indicate the operation life of the EVRF when we begin the care.
- On the left we have the drawing of a foot switch with a meter which will count the number of pulses given.

The OFF icon in the top left corner indicates that the EVRF is in “OFF” mode. By touching on “OFF” the EVRF is changed to “ON” and ready to be used.

USE

- Put a needle in the needle-holder pen
- Disinfect the area to treat
- Place the needle perpendicularly to the area to treat
- Prick so that the needle is planted in or very close to the Varicula
- Push the foot switch to give the high frequency wave
- We thermo-coagulate all 2-3mm.

A beep indicates that the impulse is transmitted.
The beep stops as soon as the duration of the impulse is finished (ex: an impulse of 0.2 S will generate 2 sound beeps, an impulse of 0.4 S will generate 4 sound beeps).

If, after the first pulse is finished, the foot switch is still activated then the “T Down” time starts. After T Down is finished and the foot switch is still activated a new pulse will be transmitted. If you don’t want to use the “T Down” feature then you need to deactivate the pedal first before a new pulse will be transmitted.

The parameters of power and duration of impulse can be modified thanks to the buttons on the bottom of the screen.

7.2.3. End of the care

To stop the care definitively, one touches the ✕ button. We return to the basic screen

7.3 EVRF Settings

These tables will give a clear overview of which settings are necessary for which vein treatment.

EVRF settings for the transcutaneous treatment		
Diameter vein	0,3 mm – 0,6 mm	0,7 mm – 1 mm
Treatment area	Face	Leg
Needle	K3i needle	K6i needle
Power (watt)	5 – 8 Max. 10	9 – 14 Max. 16
Impulse time	0,2 – 0,3 s	0,3 – 0,4 s Max. 0,5 s

EVRF settings for the CR12i and CR30i catheter		
Diameter vein	1 mm – 2 mm	2 mm – 5 mm
Catheter	CR12i	CR30i
Needle	G24 needle	G20 needle
Power (watt)	3 - 6	8 - 12
Continuous mode	Keep footswitch pressed down	Keep footswitch pressed down
Number beeps at start	4	4 - 6
Number beeps per 8 mm retraction	3	3 - 6

EVRF settings for the CR45i catheter	
Diameter vein	6 mm – 18 mm
Catheter	CR45i
Needle	6 Frenge Introducer
Power (watt)	25
Continuous mode	Keep footswitch pressed down
Number beeps at start	3
Number beeps per 0,5 cm retraction	3

WARNING! Do not send frequency through the CR45i catheter when it is longer than one minute outside the vein. This avoids damage of the device.

8. ANNUAL CONTROL FORMS

The **EVRF** must have an annual control to be able to claim with the maintenance of its MARKING EC. This control makes it possible to check all the functions of the apparatus and, particularly, the safety measures.

This chapter relates to the notebook of maintenance of the EVRF.

<table>
<tr><td colspan="2">Control of end of guarantee</td></tr>
<tr><td>Date of control to carry out:</td><td>Date of control :</td></tr>
<tr><td colspan="2">Checks carried out:

□ - Visual monitoring and cleaning of EVRF.
□ - Security’s control.
□ - Control functions of orders.
□ - Measuring of the output signals.
□ - Control of the treadle.
□ - Control pen carries needle.</td></tr>
<tr><td colspan="2">Changed components:

□ - Pen carried needle.

□ - Other components : ……...

……..</td></tr>
<tr><td>Name and visa of the controller</td><td>Name and visa of the customer:</td></tr>
</table>

Control of year 2	
Date of control to carry out:	**Date of control :**
Checks carried out: □ **- Visual monitoring and cleaning of EVRF.** □ **- Security's control.** □ **- Control functions of orders.** □ **- Measuring of the output signals.** □ **- Control of the treadle.** □ **- Control pen carries needle.**	
Changed components: □ **- Pen carried needle.** □ **- Other components : ……..** **……..**	
Name and visa of the controller	**Name and visa of the customer:**

Control of year 3	
Date of control to carry out:	**Date of control :**
Checks carried out: □ **- Visual monitoring and cleaning of EVRF.** □ **- Security's control.** □ **- Control functions of orders.** □ **- Measuring of the output signals.** □ **- Control of the treadle.** □ **- Control pen carries needle.**	
Changed components: □ **- Pen carried needle.** □ **- Other components : ……..** **……..**	
Name and visa of the controller	**Name and visa of the customer:**

Control of year 4	
Date of control to carry out:	**Date of control :**
Checks carried out: □ **- Visual monitoring and cleaning of EVRF.** □ **- Security's control.** □ **- Control functions of orders.** □ **- Measuring of the output signals.** □ **- Control of the treadle.** □ **- Control pen carries needle.**	
Changed components: □ **- Pen carried needle.** □ **- Other components : ……...** **……..**	
Name and visa of the controller	**Name and visa of the customer:**

Control of year 5	
Date of control to carry out:	**Date of control :**
Checks carried out: □ **- Visual monitoring and cleaning of EVRF.** □ **- Security's control.** □ **- Control functions of orders.** □ **- Measuring of the output signals.** □ **- Control of the treadle.** □ **- Control pen carries needle.**	
Changed components: □ **- Pen carried needle.** □ **- Other components : ……...** **……..**	
Name and visa of the controller	**Name and visa of the customer:**

Control of year 6	
Date of control to carry out:	**Date of control :**
Checks carried out: □ **- Visual monitoring and cleaning of EVRF.** □ **- Security's control.** □ **- Control functions of orders.** □ **- Measuring of the output signals.** □ **- Control of the treadle.** □ **- Control pen carries needle.**	
Changed components: □ **- Pen carried needle.** □ **- Other components : ……...** **……..**	
Name and visa of the controller	**Name and visa of the customer:**

Control of year 7	
Date of control to carry out:	**Date of control :**
Checks carried out: □ **- Visual monitoring and cleaning of EVRF.** □ **- Security's control.** □ **- Control functions of orders.** □ **- Measuring of the output signals.** □ **- Control of the treadle.** □ **- Control pen carries needle.**	
Changed components: □ **- Pen carried needle.** □ **- Other components : ……...** **……..**	
Name and visa of the controller	**Name and visa of the customer:**